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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,820	12/30/2004	Henry Daniell	1915044	3200
29653	7590	08/07/2008	EXAMINER	
ENRIQUE G. ESTEVEZ			KUBELIK, ANNE R	
255 SOUTH ORANGE AVE			ART UNIT	
SUITE 1401			PAPER NUMBER	
ORLANDO, FL 32802-3791			1638	
MAIL DATE		DELIVERY MODE		
08/07/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/519,820

Applicant(s)

DANIELL, HENRY

Examiner

Anne R. Kubelik

Art Unit

1638

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2008 and 02 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21, 28-30 and 32-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 28-30 and 32-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 June 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-21, 28-30 and 32-34 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Fig 8 remains objected to because letters within the black boxes cannot be made out.

Applicant urges that they have no current copy of Fig 8, the significance is each arrow is shown in the text above the arrow, and they wish the drawing deleted by Examiner amendment (pg 8 of the response filed 2 June 2008).

This is not found persuasive because the text above the arrow does not repeat the text in the arrow; for the one that can be made out, “psbA” is in the arrow and “promoter” is in the text above the arrow. It is assumed that for the other cases the text above the arrow also does not reflect the content of the arrow. The Figure cannot be deleted by amendment as this would result in new matter being introduced.

4. Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

5. The rejection of claims 1-5, 7-13, 15-16, 19-23 and 28-30 under 35 U.S.C. 102(b) as being anticipated by Daniell (WO 01/72959) is withdrawn in light of Applicant's arguments.
6. The rejection of claims 1-23, 28-30 and 32 under 35 U.S.C. 103(a) as being unpatentable over Daniell (WO 01/72959) is withdrawn in light of Applicant's arguments.
7. The objection to claim 21 because of an informality is withdrawn in light of Applicant's amendment of the claim.

Claim Objections

8. Claims 33-34 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits. The objection is repeated for the reasons of record as set forth in the Office action mailed 2 November 2007. Applicant's arguments filed 1 February 2008 have been fully considered but they are not persuasive.

Applicant urges that the claims have been amended to address this issue (response pg 6).

This is not found persuasive because the claims have not been amended.

9. Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 3 fails to further limit claim 1 because it recites no structure that enables expression in a chloroplast but not other types of plastids. The objection is repeated

for the reasons of record as set forth in the Office action mailed 2 November 2007. Applicant's arguments filed 1 February 2008 have been fully considered but they are not persuasive.

Applicant urges that the claims have been amended to address this issue (response pg 6).

This is not found persuasive because the amendment does not recites a structure that enables expression in a chloroplast but not other types of plastids.

Claim Rejections - 35 USC § 112

10. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

The rejection is different from the rejection set forth in the Office action mailed 2 November 2007, as applied to claims 7-8, 10-15, 21-23, 28-30 and 32. Applicant's arguments filed 1 February 2008 have been fully considered but they do not apply to this new rejection.

Claim 13 is indefinite in its recitation of the limitation "the IGF-1 is inserted into a single copy region of the plastid genome" makes no sense when talking about a vector.

Claim Rejections - 35 USC § 103

11. Claims 1-8, 14-16, 19-21, 28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hajukiewicz et al (WO 00/03022) in view of Goodman et al (1997, US Patent 5,629,175).

The claims are drawn to a plastid transformation vector comprising a first flanking sequence, a DNA encoding insulin-like growth factor (IFG-1), and a second flanking sequence,

Art Unit: 1638

wherein the DNA is operably linked to the psbA 5' UTR and 3'UTR. The claims are also drawn to an edible plant transformed with the vector.

Hajukiewicz et al teach transformation of tobacco chloroplasts (pg 27-, line 22, to pg 29, line 19) with vectors comprising an expression cassette comprising the psbA 5' promoter, a sequence encoding a mammalian protein, human growth hormone, the aadA selection marker, and the psbA 3' UTR terminator, wherein the cassettes is flanked by plastid sequences that target the expression cassette upstream of the plastid 16S rDNA (pg 25, line 24, to pg 26, line 5) to transplastomic tobacco plants that express bioactive human growth hormone at high levels (pg 42, line 20, to pg 47, line 17). Tobacco would be suitable for consumption by a mammal of one species or another.

Hajukiewicz et al do not teach expression of insulin-like growth factor in tobacco plastids.

Goodman et al teach expression of mammalian proteins, including insulin-like growth factor, in plants (column 3, lines 11-29).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of expressing a mammalian protein in tobacco plastids as taught by Hajukiewicz et al to use the insulin-like growth factor as the mammalian protein, as described in Goodman et al. One of ordinary skill in the art would have been motivated to do so because substitution of one desirable and economically important mammalian protein for another is an obvious design choice.

One of ordinary skill in the art would have been motivated to optimize the codon usage of the sequence encoding IGF for expression in plastids, as it is well known that proteins express

better when the codons they are expressed from match the genome from which they are being expressed. Thus, absence any evidence that SEQ ID NO:2, which encodes IGF, is expressed at unexpectedly higher levels than other plastid-optimized IGF coding sequences, SEQ ID NO:2 is obvious over other the sequence of IGF.

12. Claims 9-13 rejected under 35 U.S.C. 103(a) as being unpatentable over Hajukiewicz et al in view of Goodman et al as applied to claims 1-8, 14-16, 19-21, 28 and 32 above, and further in view of Daniell (WO 99/10513).

The claims are drawn to a plastid transformation vector comprising a first flanking sequence, a DNA encoding insulin-like growth factor (IFG-1), and a second flanking sequence, wherein the flanking sequences are trnI and trnA.

The teachings of Hajukiewicz et al in view of Goodman et al are discussed above. Hajukiewicz et al in view of Goodman et al do not teach trnI and trnA as the flanking sequences.

Daniell teach a plastid transformation vector that can be used to transform the chloroplasts of a wide variety of plant species (pg 9, line 1, to pg 12, line 14; pg 20, line 4, to pg 27, line 6); the vector uses trnI and trnA, which correspond to a transcriptionally active spacer region, as the flanking sequences.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of expressing insulin-like growth factor in plastids as taught by Hajukiewicz et al in view of Goodman et al to use trnI and trnA as the flanking sequences as described in Daniell. One of ordinary skill in the art would have been motivated to do so because of the advantages of these flanking sequences in expressing proteins, especially high value ones, in a wide variety of plants species (Daniell, pg 8, lines 2-10).

13. Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hajukiewicz et al in view of Goodman et al as applied to claims 1-8, 14-16, 19-21, 28 and 32 above, and further in view of Ursin et al (1997, US Patent 5,633,153).

The claims are drawn to a plastid transformation vector comprising a first flanking sequence, a DNA encoding insulin-like growth factor (IFG-1), and a second flanking sequence, wherein the vector further encodes BADH as a selectable marker.

The teachings of Hajukiewicz et al in view of Goodman et al are discussed above. Hajukiewicz et al in view of Goodman et al do not teach BADH as a selectable marker.

Ursin et al teach use of a nucleic acid encoding betaine aldehyde dehydrogenase as a selectable marker in plants (claims 1-21). The protein is targeted to the chloroplasts (column 5, lines 17-41) and the resulting plants are resistant to betaine aldehyde (column 10, lines 1-27). Ursin et al teaches that unmodified plant BADH genes were effective for selection at a wide range of betaine aldehyde concentrations (Table 3) and the effectiveness of BADH as a selectable marker in tobacco (column 8, lines 55, to column 9, line 67).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of the method of expressing insulin-like growth factor in plastids as taught by Hajukiewicz et al in view of Goodman et al to use BADH as a selectable marker as described in Ursin et al. One of ordinary skill in the art would have been motivated to do so because Ursin et al teaches the use of BADH as a selectable marker and because substitution of chloroplast transformation for chloroplast targeting of a nuclear-encoded gene is an obvious design choice.

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne Kubelik, Ph.D.
August 6, 2008

/Anne R. Kubelik/
Primary Examiner, Art Unit 1638